復星醫藥/德國藥廠BioNTech
Fosun Pharma/BioNTech

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2023年3月28日
28 March 2023

信使核糖核酸新冠疫苗
COVID-19 mRNA Vaccine

Comirnaty「復必泰」

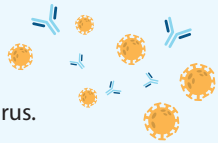
(核苷修飾 nucleoside modified)

接種須知
Vaccination Fact Sheet

衞生防護中心
Centre for Health Protection

衞生署
Department of Health

1 What Comirnaty is and what it is used for



Comirnaty is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus. It has four formulations as follows:

Comirnaty	Dosage	Eligible Group
Adult formulation	Comirnaty Original 30 micrograms/dose	Adults and adolescents aged **12** years or **above**
Paediatric formulation	Comirnaty Original 10 micrograms/dose	Children aged **5** to **11** years
Toddler formulation	Comirnaty Original 3 micrograms/dose	Toddlers aged **6** months to less than **5** years old
Comirnaty bivalent vaccine	Comirnaty Original / Omicron BA.4-5 (15/15 micrograms)@/dose	**Eligible persons** aged **12** years or **above**

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty does not contain the virus to produce immunity, it cannot give you COVID-19.

Under the Government COVID-19 Vaccination Programme, all of the four Comirnaty formulations are currently authorized for use under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K) for the specified purpose instead of registered in Hong Kong under the Pharmacy and Poisons Ordinance (Cap. 138) for use.

@ 15 micrograms mRNA encoding Original viral spike protein and 15 micrograms mRNA encoding Omicron BA.4 and BA.5 per dose. Based on the available clinical data, among subjects who received the Comirnaty bivalent vaccine or the original strain vaccine as booster after completion of primary series, the antibody level against Omicron BA.4-5 and its increment were higher after receiving the Comirnaty bivalent vaccine compared to the original strain vaccine.

2 What you need to know before you receive Comirnaty

Comirnaty should not be given[1]

- if you are allergic to previous dose of Comirnaty, or to the active substance or any of the other ingredients of this medicine including the following:

((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315) / 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159) / 1,2-Distearoyl-sn-glycero-3-phosphocholine(DSPC) / cholesterol / potassium chloride* / potassium dihydrogen phosphate* / sodium chloride* / disodium phosphate dihydrate* / trometamol^ / trometamol hydrochloride^ / sucrose / water for injections

* ingredients in Comirnaty adult formulation only
^ ingredients in Comirnaty paediatric and toddler formulations and Comirnaty bivalent vaccine only

Warnings and precautions[1]

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.

[1] Follow information provided by vaccine supplier

- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your immune system.
- There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur. Members of public should avoid strenuous exercise for one week after Comirnaty vaccination.

As with any vaccine, Comirnaty may not fully protect all those who receive it and it is not known how long you will be protected.

Children

Children should receive the age-appropriate vaccine and dosage.
Please refer to **"Points to Note and Frequently Asked Questions on COVID-19 Vaccination for Children and Adolescents"** for more details.

Other medicines and Comirnaty

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine. No data are available yet regarding the use of Comirnaty bivalent vaccine during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty can be used during pregnancy.

No data are available yet regarding the use of Comirnaty bivalent vaccine during breast-feeding, however, no effects on the breast-fed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty can be given during breast-feeding.

Considering overseas recommendations and accumulating real world data on the safety of mRNA COVID-19 vaccines in pregnant and lactating women, the Scientific Committee on Vaccine Preventable Diseases and the Scientific Committee on Emerging and Zoonotic Diseases together with the Chief Executive's expert advisory panel (JSC-EAP) recommended them to receive the mRNA vaccines Comirnaty, as for the rest of the population.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines.
Wait until these effects have worn off before you drive or use machines.

Comirnaty adult formulation contains potassium and sodium

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3 How Comirnaty is given

Comirnaty is given into a muscle of your upper arm#.

The JSC-EAP recommended intramuscular injection of the Comirnaty vaccine at mid-anterolateral thigh, especially for children and adolescents.

For recommendation on intervals between doses and number of required doses by JSC-EAP, please refer to **"How many doses of COVID-19 vaccine are recommended for me?"**. For persons recovered from COVID-19 infection, please refer to the **"Factsheet on COVID-19 Vaccination for Persons with Prior COVID-19 Infection"**.

If you have any further questions on the use of Comirnaty, ask your healthcare provider.

4 Possible side effects[1]

Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

	Side effects	may affect
Very common	• irritability (6 months to < 2 years) • injection site: pain, swelling • tiredness • headache • drowsiness (6 months to < 2 years) • muscle pain • chills • joint pain • diarrhoea • fever Some of these side effects were slightly more frequent in adolescents aged 12 to 15 years than in adults.	**more than 1 in 10 people**
Common	• injection site: redness ('very common' in 6 months to 11 years) • nausea • vomiting	**up to 1 in 10 people**
Uncommon	• enlarged lymph nodes (more frequently observed after the booster dose) • feeling unwell • arm pain • insomnia • injection site itching • allergic reactions (e.g. rash ('common' for 6 months to < 2 years), itching) • feeling weak or lack of energy/sleepy • decreased appetite ('very common' for 6 months to < 2 years) • excessive sweating • night sweats • dizziness	**up to 1 in 100 people**

	Side effects	may affect
Rare	• temporary one sided facial drooping • allergic reactions (e.g. hives, swelling of the face)	**up to 1 in 1,000 people**
Very rare	• inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain	**up to 1 in 10,000 people**
Not known	• severe allergic reaction • extensive swelling of the vaccinated limb • swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers) • a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme) • unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia) • decreased feeling or sensitivity, especially in the skin (hypoaesthesia) • heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)	**cannot be estimated from the available data**

5 Reporting of adverse events after immunization

The Department of Health ("DH") has an adverse drug reaction ("ADR") reporting system which receives adverse events following immunization (AEFIs) reports to monitor the safety of COVID-19 vaccines. If you have any suspected adverse event occurred after immunization, please alert healthcare professionals (e.g. doctors, dentists, pharmacists, nurses and Chinese Medicine Practitioners), when seeking their advice, to report the AEFIs to the DH if they consider that the AEFIs may be associated with the vaccination.

For continuously monitoring of the safety and clinical events associated with COVID-19 vaccination, your personal data collected for vaccination and your clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, may be accessed and used by DH and relevant organizations collaborated with the Government (including the University of Hong Kong) insofar as such information is necessary for the monitoring.

In situations when pain or redness at the injection site increases after 24 hours from injection; or your side effects are worrying you or do not seem to be going away in a few days, please contact your doctor.

If you do seek medical attention, make sure you tell the healthcare professionals about your vaccination details and show them your vaccination record card if available. Healthcare professionals will then make proper assessment and, if necessary, report any AEFI that is deemed medically significant to DH for further action and assessment.

Please allow the healthcare professional to report the AEFI, with your consent to passing the adverse event case information, personal and clinical data to DH for continuous monitoring the safety and clinical events associated with COVID-19 vaccination.

Message to the healthcare professionals:

Please conduct medical assessment and if you consider the AEFI associated with the vaccine is deemed medically significant, please report it to the Drug Office of the Department of Health via online reporting at the webpage

https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

If the vaccine recipient experiences serious adverse event following immunization, please refer the recipient to hospital.

☐ I have read and understood all information as provided in the factsheet and the Statement of Purposes of Collection of Personal Data, and I consent to the administration of COVID-19 Vaccination to me / my child / my ward* under the COVID-19 Vaccination Programme; and the Department of Health and the relevant organizations (collaborated with the Government (including the University of Hong Kong))'s access to and use of (i) my / my child / my ward's* personal data contained herein and (ii) my / my child / my ward's* clinical data held by the Hospital Authority and the relevant private healthcare facilities and healthcare professionals, for the purpose of continuously monitoring the safety and clinical events associated with COVID-19 Vaccination by the Department of Health insofar as such access and use are necessary for the purpose.

*Please delete as appropriate

For further information on the vaccines and side effects, please visit the website at

www.covidvaccine.gov.hk

English

हिन्दी

नेपाली

اردو

ไทย

Bahasa Indonesia

Tagalog

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বাংলা ভাষা

Tiếng Việt

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我應接種多少劑新冠疫苗？
How many doses of COVID-19 vaccine are recommended for me?

生效日期 Effective Date：
2023年4月20日
20 April 2023

請留意政府最新有關疫苗接種安排的公告。
Please refer to the latest announcement by the Government for the vaccination implementation arrangement.
網址 website : www.covidvaccine.gov.hk

2023年額外加強劑 Additional Booster in 2023

屬於以下優先組別的市民，如已完成初始劑次，不論過往已接種多少劑疫苗，於接種上一劑疫苗或感染 2019 冠狀病毒病 (以較後者為準) 至少180日後，可在 2023 年內免費接種額外的加強劑：

Citizens belonging to the following priority groups, if they have completed the initial doses, they can receive an additional vaccine booster at least 180 days after their last dose or COVID-19 infection (whichever is later) free of charge in 2023, regardless of the number of vaccine doses they received in the past:

1 年屆 50 歲或以上包括居於院舍的長者[5]
Individuals aged 50 or above (including elderly living in residential care homes)[5]

2 18 至 49 歲有長期病患的成年人[7]
Persons aged 18 to 49 years with underlying comorbidities[7]

3 6 個月大或以上免疫力弱的人士[4][5]
Persons aged 6 months or above and with immunocompromising conditions[4][5]

4 孕婦
Pregnant women

5 醫護人員
Healthcare workers

初始劑次[1][8] Initial doses	如選擇克爾來福（科興）疫苗 For CoronaVac (Sinovac) vaccine		如選擇復必泰（BioNTech）疫苗 For Comirnaty (BioNTech) vaccine	
組別 Group	第一劑至第二劑 (1st to 2nd dose) :	第二劑至第三劑 (2nd to 3rd dose) :	第一劑至第二劑 (1st to 2nd dose) :	第二劑至第三劑 (2nd to 3rd dose) :
6 個月 - 4 歲 6 months - 4 years old	28日/days	90日/days	56日/days[6]	90日/days
5 - 17 歲 / years old			56日/days[6]	150日/days
18 - 49 歲 / years old			56日/days[6]	90日/days
50歲或以上[5] 50 years or above[5]			28日/days[6]	90日/days
免疫力弱[4][5] Immunocompromised[4][5]	28日/days	28日/days	28日/days[6]	28日/days

優先組別以外市民 Citizens not belonging to priority groups

以下組別的市民，如已完成初始劑次，專家認為他們 2023年可按個人意願選擇於接種上一劑疫苗或感染2019冠狀病毒病 (以較後者為準) 至少 180 日後接種額外的加強劑。他們需要自費到私營市場接種。

An additional booster in 2023 may be considered at least 180 days after the last dose/infection (whichever is later) for the following groups of citizens based on personal choice as recommended by experts if they have completed the initial doses. They will need to get the vaccine in the private market at their own expense.

- **有長期病患的 6 個月大至 17 歲兒童及青少年[7]**
  Children and adolescents aged 6 months to 17 years with comorbidities[7]
- **18 至 49 歲的健康成人**
  Healthy adults aged 18 to 49 years

備註 Remarks :

(1) 2019冠狀病毒病康復者 COVID-19 Recovered Persons

康復人士會較從未感染人士少接種一劑疫苗。康復是指首次有文件紀錄的陽性結果後 14 天。康復人士應按下一劑的間隔接種餘下的劑次。疫苗紀錄會記錄實際接種的疫苗劑數。
舉例來說，55 歲的成人如在接種第一劑後受感染，應在康復後 90 天接種下一劑 (相當於第三劑，但在疫苗紀錄上會紀錄為第二劑) 的疫苗。

有關 2019 冠狀病毒病康復者的詳細接種安排，
請參考「曾感染 2019 冠狀病毒病人士接種新冠疫苗須知」：
https://www.covidvaccine.gov.hk/pdf/factsheet_priorCOVID19infection_CHI.pdf

Recovered persons should take one dose less than uninfected persons. Recovery is defined as 14 days after the date of first positive test. The recovered persons should receive the remaining doses according to the interval for the next dose. The actual number of doses given would be marked as the dose sequence in the vaccination record. For example, a 55-year-old man with history of infection after receiving the first dose can get the next dose (equivalent to 3rd dose but marked as 2nd dose of vaccination record) 90 days upon recovery.

For details, please refer to 'Factsheet on COVID-19 Vaccination For Persons with Prior COVID-19 Infection' at
https://www.covidvaccine.gov.hk/pdf/factsheet_priorCOVID19infection_ENG.pdf

(2) 兒童及青少年 Children and Adolescents

有關兒童及青少年的詳細接種安排，包括有關陪同人士要求、接種同意書要求及常見問題，請參考「新冠疫苗接種常見問題之兒童及青少年篇」：
https://www.covidvaccine.gov.hk/pdf/FAQ_children_adolescents_CHI.pdf

For details of the vaccination arrangement for children and adolescents, including the accompany requirements and consent form requirements, please refer to the 'FAQs on COVID-19 Vaccination for Children and Adolescents' at
https://www.covidvaccine.gov.hk/pdf/FAQ_children_adolescents_ENG.pdf

(3) 市民在可能的情況下應盡量以同一款疫苗完成首兩劑接種。如因首劑出現嚴重副作用而需要接種另一款疫苗的人士，請向你的主診醫生或家庭醫生取得相關醫生證明信 (當中包括建議改為接種另一款疫苗的醫學原因)，到疫苗接種地點。醫護人員會考慮個別情況，安排接種。 接種首兩劑疫苗後，可以選擇接種同款或另一款額外劑數新冠疫苗以加強保護。

Citizens are advised to complete the first two doses with the same product when possible. For those who developed severe side effects after the initial dose and would need to receive another brand for second dose, please obtain relevant doctor's certification letter (including the reasons to receive another brand for second dose) from your attending doctor or family doctor and attend the vaccination venue. Health care professionals will arrange the vaccination based on individual circumstances. After the completion of first two doses, you may choose to receive the same type or another type of additional dose(s) of COVID-19 vaccines to enhance the protection.

(4) 免疫力弱人士包括：
Immunocompromised persons include:

1. 現正接受或過去12 個月內曾接受腫瘤或血癌免疫抑制治療
   Cancer or hematological malignancy on active immunosuppressive treatment now or in the past 12 months
2. 曾接受器官移植或幹細胞移植並正接受免疫抑制治療
   Recipients of solid organ transplant or stem cell transplant on immunosuppressive treatment
3. 重度原發性免疫缺陷症或正長期接受透析治療
   Severe primary immunodeficiency or on chronic dialysis
4. 晚期或未接受治療的愛滋病毒感染
   Advanced or untreated HIV disease
5. 正接受免疫抑制藥物或過去 6 個月內曾接受過免疫抑制性化療或放射治療
   On active immunosuppressive drugs, or immunosuppressive chemotherapy / radiotherapy in past 6 months

(5) 以下市民如只完成首三劑疫苗，建議他們在第三劑後 90 日免費接種下一劑疫苗：
- **50 歲或以上從未感染的人士**；或
- **6 個月大或以上從未感染的免疫力弱的人士**

The following citizens if only completed three doses, they are recommended to receive the next dose 90 days after 3rd dose free of charge:
- **Uninfected individuals aged 50 or above**; or
- **Uninfected persons aged 6 months or above and with immunocompromising conditions**

(6) 有個別需要人士經考慮個人風險及益處，並在知情同意下，該間距可縮短至不少於三星期。
This dosing interval could be shortened to a minimum of three weeks for those with personal needs under informed consent after consideration of individual risk and benefit.

(7) 有長期病患人士包括：
Persons with underlying comorbidities:

1. 長期心血管疾病 (患有高血壓但無引發併發症的人除外)、肺病
   Chronic cardiovascular (except hypertension without complications), lung diseases
2. 新陳代謝疾病或腎病、肥胖 (體重指數 30 或以上)
   Metabolic or kidney diseases, obesity (Body Mass Index 30 or above)
3. 患有長期神經系統疾病，以致危及呼吸功能，或難於處理呼吸道分泌物，或因此病增加異物吸入肺內風險的人士，或欠缺自我照顧能力的人士
   Chronic neurological conditions that can compromise respiratory functions or the handling of respiratory secretions, or increase the risk of aspiration, or those who lack the ability to take care of themselves
4. 長期服用亞士匹林的兒童和青少年 (6 個月至 18 歲)
   Children and adolescents (aged 6 months to 18 years) on long-term aspirin therapy

(8) 年滿六個月的市民若從未感染 2019 冠狀病毒病，可免費接種首三劑新冠疫苗。
Citizens aged 6 months or above can receive the first three doses of COVID-19 vaccine free of charge if they have never been infected with COVID-19.

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最新資訊請參閱網上版本 Please refer to online version for most updated information.

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更多防疫資訊
For more information on fighting the virus:
www.coronavirus.gov.hk

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